

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

PERRIGO COMPANY AND
SUBSIDIARIES,

Plaintiff,

v.

UNITED STATES OF AMERICA,

Defendant.

No. 1:17-cv-00737

The Hon. Robert J. Jonker

UNITED STATES' ANSWER

The Defendant responds to the Plaintiff's complaint as follows:¹

Preliminary Statement

1. Plaintiff brings this action pursuant to 28 U.S.C. section 1346(a)(1) and sections 6532 and 7422 of the Internal Revenue Code of 1986 ("IRC") for the recovery of Federal income taxes, penalties, and interest erroneously and illegally assessed and collected by the Internal Revenue Service ("IRS"), plus statutory interest thereon from the dates of payment. Plaintiff overpaid Federal income taxes for its 52-53 week tax years ending June 27, 2009, June 26, 2010, June 25, 2011, and June 30, 2012 (the "2009 tax year," "2010 tax year," "2011 tax year," and "2012 tax year," respectively).

ANSWER: Admits that Plaintiff seeks to recover federal income taxes, penalties and interest collected by the IRS, plus statutory interest; admits that Plaintiff invokes the federal statutes referred to in the allegation; otherwise, denies.

2. Plaintiff overpaid taxes, penalties, and interest with respect to transactions involving the purchase, distribution, and sale of store-brand over-the-counter ("OTC")

¹ Defendant's responses appear in bold type.

pharmaceutical products containing the active ingredient omeprazole in the 2009, 2010, 2011, and 2012 tax years.

ANSWER: Denies.

3. Plaintiff overpaid taxes, penalties, and interest with respect to amounts of legal fees Plaintiff paid or incurred defending against certain patent infringement lawsuits in the 2011 and 2012 tax years.

ANSWER: Denies.

4. Plaintiff timely filed claims for refund with the IRS for the 2009, 2010, 2011, and 2012 tax years, seeking refunds of Federal income taxes, penalties, and assessed interest, plus interest thereon as allowed by law for each of the years. The IRS disallowed these refund claims and Plaintiff timely files this complaint within the period of limitations provided by IRC section 6532.

ANSWER: Admits.

5. For the 2009 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$37,221,289, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

ANSWER: Admits that Plaintiff claims a refund of \$37,221,289, plus statutory interest; otherwise, denies.

6. For the 2010 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$61,462,133, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

ANSWER: Admits that Plaintiff claims a refund of \$61,462,133, plus statutory interest; otherwise, denies.

7. For the 2011 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$40,148,650, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

ANSWER: Admits that Plaintiff claims a refund of \$40,148,650, plus statutory interest; otherwise, denies.

8. For the 2012 tax year, Plaintiff claims a refund of tax, penalties, and assessed interest of \$24,730,253, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus statutory interest on the amount to be refunded.

ANSWER: Admits that Plaintiff claims a refund of \$24,730,253, plus statutory interest; otherwise, denies.

Parties

9. Plaintiff is the common parent of an affiliated group of corporations that filed a consolidated Federal income tax return for each tax year at issue in this action. Pursuant to Treasury Regulation section 1.1502-77, Plaintiff is authorized to bring this action on behalf of the entities included in the consolidated group. Plaintiff's principal place of business is and, at all times relevant to this action was, in Allegan, Michigan.

ANSWER: Admits that Plaintiff is the common parent of an affiliated group of corporations that filed a consolidated federal income tax return for each tax year at issue; admits that Plaintiff has brought this action on behalf of the entities included in the consolidated group; admits that Plaintiff's principal place of business is, and at all times relevant to this action was, Allegan, Michigan; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

10. Defendant is the United States of America.

ANSWER: Admits.

Jurisdiction and Venue

11. This Court has jurisdiction over this action pursuant to 28 U.S.C. section 1346(a)(1) and IRC section 7422.

ANSWER: Is not aware of any impediments to the Court's jurisdiction over this dispute other than as described in the United States' Second Additional Defense. To the extent the remaining allegations state Plaintiff's understanding of jurisdictional requirements, the allegations constitute legal conclusions and do not require a response.

12. Venue is proper in this Court pursuant to 28 U.S.C. section 1402(a)(2) because Plaintiff's principal place of business is located within this judicial district.

ANSWER: Admits that venue is proper in this Court and that Plaintiff's principal place of business is located within the judicial district. To the extent the remaining allegations state Plaintiff's understanding of venue requirements, the allegations constitute legal conclusions and do not require a response.

Background Statement

Omeprazole

13. Plaintiff is a leading manufacturer and distributor of store-brand OTC and generic pharmaceutical products.

ANSWER: Admits.

14. Omeprazole is a proton pump inhibitor useful in treating heartburn, ulcers, and gastro-esophageal reflux disease.

ANSWER: Admits.

15. Omeprazole base is the active ingredient of Prilosec (“Prilosec Rx”), a patented drug developed by the pharmaceutical company AstraZeneca. Prilosec Rx was first approved and marketed in the United States as a prescription drug in 1989.

ANSWER: Admits that omeprazole is the active ingredient in Prilosec; admits that Prilosec was a drug developed by AstraZeneca for which AstraZeneca asserted patent protection; admits that Prilosec was approved by the U.S. Food and Drug Administration in 1989 and marketed in the United States as a prescription drug; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

16. In 2000, AstraZeneca filed an application with the Food and Drug Administration (“FDA”) seeking approval of Prilosec OTC, an OTC version of Prilosec Rx with omeprazole magnesium, rather than omeprazole base, as the active ingredient. Upon obtaining FDA approval in 2003, AstraZeneca began selling Prilosec OTC in the United States. Under FDA regulations, Prilosec OTC became the reference drug for subsequent FDA filings by OTC competitors.

ANSWER: Admits that AstraZeneca filed an application with the FDA seeking approval for Prilosec OTC; admits that the active ingredient for Prilosec OTC was omeprazole magnesium; admits that FDA approval was obtained in 2003; admits that AstraZeneca afterward began selling Prilosec OTC in the United States; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

17. Beginning in 2002 and continuing into 2006, Plaintiff attempted to formulate a generic omeprazole product as an alternative to Prilosec OTC (“generic OTC omeprazole”) but ultimately was unsuccessful.

ANSWER: Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

18. During 2003 and 2004, Plaintiff also looked to Schwarz Pharmaceutical to formulate generic OTC omeprazole, but Schwarz Pharmaceutical likewise was unsuccessful.

ANSWER: Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

19. During 2005 through 2012, and at all times relevant to this action, L. Perrigo Company (“LPC”) was a member of Plaintiff’s consolidated group.

ANSWER: Admits.

20. In August 2005, LPC entered into a Supply & Distribution Agreement (the “Contract”) with Dexcel Pharma Technologies, Ltd. (“Dexcel”), an unrelated Israeli pharmaceutical manufacturer. The Contract related to a potential generic OTC omeprazole product for the United States market that Dexcel was trying to develop and manufacture. As of the date of the Contract, Dexcel had not yet succeeded in developing a generic OTC omeprazole product for the United States market.

ANSWER: Admits that a document entitled Supply & Distribution Agreement exists; admits that the document purports to be executed by LPC and Dexcel; admits that the document purports to relate to a generic omeprazole product as described therein; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

21. Under the Contract, Dexcel was responsible for formulating and developing generic OTC omeprazole in tablet form and obtaining FDA approval for the product. If the FDA approved the product, Dexcel would be responsible for manufacturing the product.

ANSWER: Admits that a document entitled Supply & Distribution Agreement exists; admits that the document purports to relate to a generic omeprazole product; admits that the document purports to assign certain functions or responsibilities to Dexcel; admits that the document purports to address FDA approvals as described therein; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

22. Under the Contract, if Dexcel succeeded in obtaining FDA approval for generic OTC omeprazole, LPC would be responsible for distributing the product in the United States. LPC agreed to make up to \$600,000 in milestone payments to Dexcel during drug development and also to reimburse Dexcel for up to \$500,000 in litigation expenses incurred in defending against any patent infringement suits brought against Dexcel in connection with the product.

ANSWER: Admits that a document entitled Supply & Distribution Agreement exists; admits that the document purports to relate to a generic omeprazole product; admits that the document purports to assign certain functions or responsibilities to LPC; admits that the document purports to set forth financial arrangements between LPC and Dexcel as described therein; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

23. The Contract provided that the parties would equally divide net profits from United States sales of the product after certain cost allowances to each party.

ANSWER: Admits that a document entitled Supply & Distribution Agreement

exists; admits that the document purports to set forth financial arrangements between LPC and Dexcel as described therein; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

24. Perrigo Israel Trading Limited Partnership (“PITLP”) is a partnership organized under the laws of the State of Israel. PITLP was formed in 2006. PITLP was during all relevant years treated as a corporation for United States tax purposes and a partnership for Israeli tax purposes. As a controlled foreign corporation, PITLP is not a member of Plaintiff’s consolidated tax return group.

ANSWER: Admits that PITLP is not a member of Plaintiff’s consolidated tax return group; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

25. Perrigo LLC (“LLC”) is a limited liability company organized under Delaware law in 2006. LLC was for all relevant years treated as a disregarded entity for United States tax purposes. PITLP is LLC’s sole member, and for United States tax purposes all of the assets, liabilities, and activities of LLC are treated as the assets, liabilities, and activities of PITLP. Henceforth, PITLP and LLC are referred to in this complaint jointly as “PITLP/LLC.”

ANSWER: Admits Perrigo LLC registered as a limited liability company under Delaware law on or about November 29, 2006; admits that Perrigo characterizes LLC as a disregarded entity for United States tax purposes; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the factual allegations in this paragraph.

26. PITLP/LLC was formed as part of Plaintiff's intended internationalization of its business operations.

ANSWER: Denies.

27. PITLP/LLC was formed in accordance with professional tax advice provided to Plaintiff by the global professional services firm Ernst & Young LLP ("EY").

ANSWER: Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

28. PITLP/LLC conducted business activity.

ANSWER: Denies.

29. PITLP/LLC is a legitimate entity that should be respected for tax purposes and is not a sham.

ANSWER: Denies.

30. Effective November 29, 2006, LPC and PITLP/LLC entered into an agreement (the "Assignment Agreement") under which LPC assigned its rights and obligations under the Contract to LLC. PITLP/LLC paid LPC \$877,832 as consideration for the assignment. The price paid by PITLP/LLC was based on an economic study prepared by EY.

ANSWER: Admits that a document purporting to be an assignment of a supply and distribution agreement exists; admits that the document purports to be executed by LPC and Perrigo Israel LLC; admits that a document exists purporting to have been prepared by EY addressing the purported assignment; denies that PITLP/LLC paid LPC consideration for any such purported assignment; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

31. PITLP/LLC and LPC entered into a Sales and Distribution Agreement effective as of November 29, 2006 (the “Sales & Distribution Agreement”). Under the Sales & Distribution Agreement, if approved by the FDA, LPC would distribute Dexcel’s generic OTC omeprazole on behalf of PITLP/LLC. The Sales & Distribution Agreement provided LPC with a guaranteed return on its distribution activities and a percentage of the residual profits from the sales of generic OTC omeprazole. The agreed consideration to be paid to LPC was based on an economic study prepared by EY.

ANSWER: Admits that a document entitled Sales and Distribution Agreement exists; admits that the document purports to be executed by LPC and Perrigo LLC; admits that the document purports to assign certain functions or responsibilities to LPC; admits that the document purports to set forth financial arrangements between LPC and Perrigo LLC; admits that a document exists purporting to have been prepared by EY addressing the purported assignment; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

32. The Assignment Agreement and Sales & Distribution Agreement each had economic substance and should be respected for tax purposes.

ANSWER: Denies.

33. The Assignment Agreement shifted ownership of the legal rights and obligations under the Contract from LPC to PITLP/LLC. After the assignment, PITLP/LLC assumed all risks associated with the approval and marketing of the generic OTC omeprazole product.

ANSWER: Denies.

34. The Assignment Agreement was not an anticipatory assignment of income.

ANSWER: Denies.

35. The Assignment Agreement and Sales & Distribution Agreement had non-tax business purposes and were entered into consistent with professional advice from EY.

ANSWER: Denies that the purported agreements had non-tax business purposes; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

36. In February 2006, Dexcel filed a New Drug Application (“NDA”) with the FDA seeking approval of the generic OTC omeprazole product together with a “Paragraph IV certification” of non-infringement of patents relating to Prilosec Rx. Dexcel filed an NDA, rather than an Abbreviated New Drug Application (“ANDA”), because Dexcel’s generic OTC omeprazole product had a different active ingredient (omeprazole base) than the active ingredient of Prilosec OTC (omeprazole magnesium). Accordingly, a “compare to” statement was not allowed with respect to Prilosec OTC.

ANSWER: Admits an NDA was filed on behalf of Dexcel with the FDA in February 2006 seeking approval of a generic OTC omeprazole product; admits that Dexcel’s submissions contained certain so-called Paragraph IV certifications relating to Prilosec products; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

37. In May 2006, AstraZeneca sued Dexcel alleging infringement of patents relating to Prilosec Rx. Pursuant to 21 U.S.C. section 355(c)(3)(C), the patent infringement suit filed by AstraZeneca automatically triggered a 30-month stay for FDA approval of Dexcel’s generic OTC omeprazole. Plaintiff was not a party to the AstraZeneca patent infringement lawsuit and generally was barred from any knowledge of the proceedings under the Contract.

ANSWER: Admits that in May 2006, AstraZeneca sued Dexcel alleging

infringement of patents concerning Prilosec; admits that the litigation resulted in deferral of FDA final approval with respect to Dexcel's NDA as described on page 2 of letter from the FDA to Dexcel's agent of June 14, 2007; admits that Plaintiff was not a named party in the patent infringement suit referred to; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

38. AstraZeneca and Dexcel settled the patent infringement dispute in September 2007, approximately one year before the expiration of the 30-month stay. The settlement allowed Dexcel to market its generic OTC omeprazole product in the United States upon receipt of FDA approval. Plaintiff was not involved in settlement negotiations between Dexcel and AstraZeneca. The early conclusion of the patent infringement litigation was unexpected and surprising to Plaintiff.

ANSWER: Admits that AstraZeneca and Dexcel settled the patent infringement dispute in September 2007; admits that the terms of the settlement permitted Dexcel to sell its generic OTC omeprazole product in the United States as of October 21, 2007, dependent upon receipt of FDA approval; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

39. The FDA approved Dexcel's generic OTC omeprazole product for sale in the United States in December 2007.

ANSWER: Admits.

40. Prior to FDA approval of Dexcel's generic OTC omeprazole product, PITLP/LLC faced the financial obligations imposed by the Contract and considerable risks with respect to whether a generic OTC omeprazole product would be brought to market in the United States, including but not limited to, the risks outside of PITLP's/LLC's control that: (i) the FDA would

not approve Dexcel's generic OTC omeprazole tablet; (ii) AstraZeneca, through its patent infringement suit, would block, delay or permanently enjoin sales of Dexcel's generic OTC omeprazole tablet; and (iii) competitors would beat Dexcel to market with a competing generic OTC omeprazole product and significantly reduce available market share. From 2008 onwards, PITLP/LLC faced significant risk that competing omeprazole products would enter the market and erode market share and prices and drive down potential profits from the product.

ANSWER: Denies.

41. By December 31, 2007, six companies had generic versions of Prilosec Rx on the market. Currently, nine companies produce ten generic versions of Prilosec Rx.

ANSWER: Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

42. Beginning in early 2008, and continuing into subsequent years, Dexcel manufactured generic OTC omeprazole tablets, which were distributed pursuant to the Contract, the Assignment Agreement, and the Sales & Distribution Agreement.

ANSWER: Admits Dexcel manufactured generic OTC omeprazole tablets; denies that the tablets were distributed pursuant to the purported Assignment Agreement or the Sales & Distribution Agreement; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

43. During the 52-53 week tax year ending on June 30, 2007 (the "2007 tax year") and the first eight months of the 52-53 week tax year ending on June 28, 2008 (the "2008 tax year"), PITLP/LLC had substantial capital available to it through its parent company, Perrigo

UK FINCO Limited Partnership, a United Kingdom entity treated as a corporation for United States tax purposes.

ANSWER: Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

44. During the last four months of the 2008 tax year, and during the entirety of the 2009-2012 tax years, PITLP/LLC had substantial capital, income, and accounts; was performing under three contracts with unrelated parties; was distributing substantial dividends, and making substantial loans; and was otherwise engaged in substantial business activities. PITLP/LLC also was making payments to Plaintiff for management services, making payments to LPC for marketing and project management services, and making payments to Perrigo Research and Development Company, a member of the Plaintiff's consolidated group, for research and development services.

ANSWER: Denies that PITLP/LLC was engaged in substantial business activities; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

¶ IV ANDA Litigation Defense Costs

45. In the ordinary course of its business, Plaintiff incurs legal costs to defend against actual and threatened civil actions alleging that Plaintiff's manufacture and sale of generic pharmaceutical products infringe on another party's rights that are protected under United States patent laws. Under established principles of tax law such patent litigation defense costs are deductible as ordinary and necessary business expenses.

ANSWER: Admits that Plaintiff has incurred legal costs to defend against actual and threatened civil actions alleging that Plaintiff's manufacture and sale of generic

pharmaceutical products infringe on another party's rights that are protected under United States patent laws; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of fact in this paragraph.

46. In general, a company seeking approval of a new drug must file an NDA with the FDA demonstrating that the drug is safe and effective for the indicated purposes. A company seeking FDA approval to manufacture and sell a generic version of the previously approved drug may file instead an ANDA with the FDA together with a "Paragraph IV certification" of non-infringement for the generic drug (a "¶ IV ANDA"). Compared to an NDA, an ANDA requires a lesser showing that the generic drug for which approval is sought is bioequivalent to the previously approved brand name version of the drug.

ANSWER: Denies to the extent that the allegations in this paragraph conflate submission of a NDA that is subject to 21 U.S.C. § 355(b)(2) (permitting an applicant to refer back to a previously-approved drug, but still potentially requiring submission of preclinical and clinical data) with submission of a NDA that is not subject to 21 U.S.C. § 355(b)(2); admits that a company seeking FDA approval to manufacture and sell a generic version of a previously-approved "reference listed drug" may file an ANDA together with certifications relating to patents, if any, associated with the owner of the previously-approved drug; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

47. Upon receiving notice of a ¶ IV ANDA filing, a patent holder may file suit alleging that the proposed generic drug would infringe on the holder's patent rights with respect

to a related brand name drug product and cannot be legally sold until the infringed patents have expired.

ANSWER: Admits that generally a patent holder receiving a paragraph IV notification from an ANDA applicant may file a patent infringement suit; otherwise, this allegation restates law and requires no response.

48. During the 2011 and 2012 tax years, Plaintiff was a named defendant in several patent infringement lawsuits challenging its right to manufacture and sell generic pharmaceuticals that were the subject of ¶ IV ANDAs filed with the FDA. During its 2011 and 2012 tax years, Plaintiff incurred legal fees and expenses to defend against these patent infringement suits. On its Federal income tax returns for these years, Plaintiff deducted as ordinary and necessary business expenses the costs it paid or incurred to defend against patent infringement suits filed in response to ¶ IV ANDA filings.

ANSWER: Admits that Plaintiff identified a deduction of such costs on its tax returns; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

TAX FILINGS, ADJUSTMENTS, AND CLAIMS

49. Plaintiff timely filed consolidated Federal income tax returns for its 2007 and 2008 tax years and made payments to the IRS in accordance with the contractual arrangements described above and in the amounts shown on the tax returns for the 2007 and 2008 tax years within the time prescribed by law.

ANSWER: Admits that Plaintiff timely filed consolidated federal income tax returns for its 2007 and 2008 tax years; admits Plaintiff made payments to the IRS in accordance with amounts shown on its tax returns for the 2007 and 2008 tax years; and

otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

50. The IRS conducted routine civil examinations of Plaintiff's Federal income tax returns for the 2007 and 2008 tax years.

ANSWER: Admits that the IRS conducted a civil examination of Plaintiff's federal income tax returns for the 2007 and 2008 tax years.

51. In the course of the examination of Plaintiff's 2007 and 2008 tax years, the IRS assigned a skilled international examiner to audit issues associated with Perrigo's international operations and transfer pricing positions.

ANSWER: Admits.

52. The IRS requested from Plaintiff extensive information regarding the formation, operation, and functions of PITLP/LLC; the relationship between Dexcel and Plaintiff; the intercompany arrangements between Plaintiff, LPC, and PITLP/LLC; the accounting for intercompany transactions relating to the purchase and sale of generic OTC omeprazole; issues relating to the business purpose, substance and form of PITLP/LLC; pricing of the Assignment Agreement and other issues related to the assignment of the Contract; and transfer pricing reports prepared by EY. In response to the numerous questions and requests for information, Perrigo provided extensive and detailed information to the international specialist.

ANSWER: Admits that in the course of the examination of Plaintiff's 2007 and 2008 tax years, the IRS requested certain information from the Plaintiff regarding its relationship with Dexcel and with PITLP/LLC; and denies that in the course of the examination of Plaintiff's 2007 and 2008 tax years, Perrigo provided extensive or detailed information sufficient to evaluate the intercompany arrangements between Plaintiff, LPC,

and PITLP/LLC, or intercompany transactions relating to the purchase and sale of generic OTC omeprazole, within the time allotted for the examination.

53. Upon conclusion of its extensive examination of the events, entities and transfer pricing positions with respect to generic OTC omeprazole for Plaintiffs 2007 and 2008 tax years, the IRS did not propose an adjustment to Plaintiffs income or otherwise challenge Plaintiffs tax reporting position. In particular, the IRS did not: (i) propose an income adjustment related to the pricing or substance of the assignment of the Contract; (ii) challenge the conclusion that Plaintiffs transfer pricing reporting positions met the arm's length standard and other requirements of section 482; or (iii) propose accuracy-related penalties under IRC section 6662.

ANSWER: Admits that the IRS did not propose an adjustment regarding PITLP/LLC during the 2007-2008 audit cycle; and denies that in the course of the examination of Plaintiff's 2007 and 2008 tax years, Perrigo provided extensive or detailed information sufficient to evaluate the intercompany arrangements between Plaintiff, LPC, and PITLP/LLC, or intercompany transactions relating to the purchase and sale of generic OTC omeprazole, within the time allotted for the examination.

54. In the course of the examination of Plaintiff's 2007 and 2008 tax years, the IRS also requested from Plaintiff information regarding the generic pharmaceutical product desloratadine and the assignment of a separate agreement relating to desloratadine to PITLP/LLC during the 2007 tax year. Since the assignment, PITLP/LLC has financed the development of desloratadine without any commercial success. Upon conclusion of its extensive examination of the events, entities and transfer pricing positions with respect to desloratadine, the IRS did not

propose an adjustment to Plaintiff's income or otherwise challenge Plaintiff's tax reporting position.

ANSWER: Admits that the IRS requested certain information related to desloratadine in the 2007-2008 audit cycle and that Plaintiff provided some such information; admits that the IRS proposed no adjustment in the 2007-2008 audit cycle related to desloratadine; denies that PITLP/LLC financed the development of desloratadine; and otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

55. Plaintiff timely filed consolidated Federal income tax returns for its 2009, 2010, 2011, and 2012 tax years and made payments to the IRS in accordance with the contractual arrangements described above and in the amounts shown on the tax returns for the 2009, 2010, 2011, and 2012 tax years within the time period prescribed by law.

ANSWER: Admits that Plaintiff timely filed consolidated Federal income tax returns for its 2009, 2010, 2011, and 2012 tax years and made payments to the IRS; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

56. The IRS conducted routine civil examinations of Plaintiff's Federal income tax returns for the 2009, 2010, 2011, and 2012 tax years. The IRS relied heavily on hindsight to conduct a second audit and reopen issues previously examined and unadjusted during the examination of Plaintiff's 2007 and 2008 tax years. The IRS asserted deficiencies in tax and later made assessments with respect to the previously described transactions and arrangements, allocating all or virtually all of the income from United States sales of generic OTC omeprazole

to Plaintiff. Plaintiff has fully paid the assessed amounts of tax, interest, and penalties to the IRS for the 2009, 2010, 2011, and 2012 tax years.

ANSWER: Admits that the IRS conducted examinations of Plaintiff's tax returns for 2009, 2010, 2011, and 2012; admits that the IRS identified deficiencies in tax and made assessments with respect to Plaintiff's omeprazole business, admits that the IRS adjustments allocated all of the reported income of PITLP/LLC to Plaintiff; admits, alternatively, the IRS allocated all or virtually all of the income from United States sales of generic OTC omeprazole to Plaintiff; admits Plaintiff has fully paid the assessed amounts of tax, interest, and penalties to the IRS for the 2009, 2010, 2011, and 2012 tax years; otherwise, denies.

57. By letter dated May 5, 2015, the IRS designated for litigation the issues pertaining to generic OTC omeprazole for the 2009 and 2010 tax years.

ANSWER: Admits that the IRS designated for litigation certain issues in connection with Plaintiff's generic OTC omeprazole business for the 2009 and 2010 tax years; and avers that the designation of these issues by the IRS does not limit the United States from raising additional issues in this action.

58. On June 11, 2015, Plaintiff timely filed claims for refund for the 2009 and 2010 tax years, seeking refunds of overpaid Federal income taxes, penalties, and assessed interest, plus statutory interest thereon as allowed by law.

ANSWER: Admits that, on or about June 11, 2015, Plaintiff timely filed claims for refund for the 2009 and 2010 tax years, seeking refunds of federal income taxes, penalties, and assessed interest, plus statutory interest thereon; otherwise, denies.

59. On June 7, 2017, Plaintiff timely filed claims for refund for the 2011 and 2012 tax years, seeking refunds of overpaid Federal income taxes, penalties, and assessed interest, plus statutory interest thereon as allowed by law.

ANSWER: Admits that, on or about June 7, 2017, Plaintiff timely filed claims for refund for the 2011 and 2012 tax years, seeking refunds of Federal income taxes, penalties, and assessed interest, plus statutory interest thereon; otherwise, denies.

60. By certified letters dated August 18, 2015, the IRS disallowed the claims for refund that Plaintiff filed for the 2009 and 2010 tax years. No amounts of the requested refunds have been credited, remitted, refunded, or repaid to Plaintiff or to anyone on its account.

ANSWER: Admits.

61. By certified letters dated July 11, 2017, the IRS disallowed the claims for refund that Plaintiff filed for the 2011 and 2012 tax years. No amounts of the requested refunds have been credited, remitted, refunded, or repaid to Plaintiff or to anyone on its account.

ANSWER: Admits.

62. Plaintiff is and at all relevant times has been the sole owner of these refund claims and has made no assignment of the claims. No action on these claims has been taken by the Congress of the United States or by any departments of the Federal government, other than the actions of the IRS described above. No other suit or process is pending on the claims in any other court.

ANSWER: Admits that no action on these claims has been taken by the Congress of the United States or by any departments of the Federal government, other than the actions of the IRS described above; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

63. The statute of limitations on assessment under IRC section 6501 has expired for all tax years prior to the 2009 tax year.

ANSWER: Admits that the three-year period specified by IRC Section 6501(a) for assessment with respect to the consolidated federal income tax returns filed by Plaintiff for tax years prior to 2009 has lapsed; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

IRS ADJUSTMENT THEORIES

64. With respect to the generic OTC omeprazole transaction described above, the IRS denied Plaintiff's claims for refund based on a variety of theories asserted in its original determinations, some of which are inconsistent with each other and mutually exclusive.

ANSWER: Admits that the IRS denied Plaintiff's claims for refund; admits that the IRS notices of deficiency sent to Plaintiff for the tax periods at issue refer to a variety of reasons in support of the IRS's adjustments, certain of which were stated in the alternative; denies that the reasons set forth in the notices were incorrect; and avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff's tax returns.

65. First, the IRS contends that PITLP/LLC is a sham entity that must be disregarded for Federal income tax purposes (the "sham entity theory").

ANSWER: Admits that this contention was identified by the IRS in notices of deficiency issued to Plaintiff; and avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff's tax returns.

66. Second, the IRS contends that the Assignment Agreement should be disregarded because the assignment lacks economic substance for Federal income tax purposes (the “sham transaction theory”).

ANSWER: Admits that this contention was identified by the IRS in the notices of deficiency issued to Plaintiff; denies that the IRS notices of deficiency identified this contention as a “sham transaction theory;” and avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff’s tax returns.

67. Third, the IRS contends that the assignment-of-income doctrine applies to attribute income from the sale of generic OTC omeprazole from PITLP/LLC to LPC (the “assignment-of-income theory”).

ANSWER: Admits that this contention was identified by the IRS in notices of deficiency issued to Plaintiff; and avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff’s tax returns.

68. The sham entity theory, the sham transaction theory and the assignment-of-income theory are referred to herein as the “primary common-law theories.”

ANSWER: This statement does not constitute a factual allegation and requires no response.

69. As an alternative to the foregoing primary common-law theories, the IRS contends that most of the income from sales of generic OTC omeprazole should be reallocated from PITLP/LLC to Plaintiff under IRC section 482 and the Treasury Regulations thereunder (the “Section 482 Alternative Theory”).

ANSWER: Admits that this contention was identified by the IRS in notices of deficiency issued to Plaintiff; and avers that the United States is not bound by IRS

contentions made in the context of the examination of Plaintiff's tax returns.

70. The adjustments to Plaintiff's taxable income for the 2009, 2010, 2011, and 2012 tax years under the IRS's primary common-law theories result from the reallocation of 100% of PITLP's/LLC's net income to Plaintiff. The adjustments to Plaintiff's taxable income for the 2009, 2010, 2011, and 2012 tax years under the IRS's Section 482 Alternative Theory results from the reallocation of nearly all of PITLP's/LLC's income to Plaintiff.

ANSWER: Admits that the adjustments to Plaintiff's taxable income for the 2009, 2010, 2011, and 2012 tax years in IRS notices of deficiency pursuant to the sham entity, economic substance, and assignment of income common-law doctrines reflect the reallocation of 100% of PITLP's/LLC's purported income to Plaintiff; admits that the adjustments to Plaintiff's taxable income for the 2009, 2010, 2011, and 2012 tax years reflected in the IRS notices of deficiency pursuant to Section 482 reflect the reallocation of nearly all of PITLP's/LLC's purported income to Plaintiff; and otherwise lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph.

71. With respect to the adjustments related to generic OTC omeprazole, the IRS bases its assessments on its primary common-law theories, not the Section 482 Alternative Theory. Plaintiff paid the full amount of these assessments.

ANSWER: Admits that the amount of the tax assessments reflect adjustments in the IRS notices of deficiency based on the sham entity, economic substance, and assignment of income common-law doctrines, not Section 482; and admits that Plaintiff paid the full amount of these assessments.

72. In addition, the IRS asserts mutually exclusive penalties for each of the 2009, 2010, 2011, and 2012 tax years under four alternative theories.

ANSWER: Admits that the IRS notices of deficiency reflect multiple penalties asserted by the IRS for each of the 2009, 2010, 2011, and 2012 tax years under four alternative bases.

73. Under its primary common-law theories, the IRS asserts a 20% substantial understatement penalty, citing IRC sections 6662(a), 6662(b)(2), and 6662(d) (the “20% Substantial Understatement Penalty”).

ANSWER: Admits that the IRS notices of deficiency asserted an alternative 20% understatement penalty, citing IRC sections 6662(a), 6662(b)(2), and 6662(d).

74. Under its primary common-law theories, the IRS asserts an alternative 20% negligence or disregard of rules or regulations penalty, citing IRC sections 6662(a), 6662(b)(1), and 6662(c) (the “20% Negligence or Disregard Penalty”).

ANSWER: Admits that the IRS notices of deficiency asserted an alternative 20% negligence or disregard of rules or regulations penalty, citing IRC sections 6662(a), 6662(b)(1), and 6662(c).

75. Under its Section 482 Alternative Theory, the IRS asserts a 40% gross valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), 6662(e)(1)(B)(ii), and 6662(h)(2)(A)(iii) (the “40% Section 482 Penalty”).

ANSWER: Admits that the IRS notices of deficiency asserted a 40% gross valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), 6662(e), and 6662(h).

76. Under its Section 482 Alternative Theory, and in alternative to the 40% Section 482 Penalty, the IRS asserts a 20% substantial valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), and 6662(e)(1)(B)(ii) (the “20% Section 482 Penalty”).

ANSWER: Admits that the IRS notices of deficiency asserted a 20% substantial valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), and 6662(e).

77. Because the IRS could only assess one of these penalties, it chose to assess the greater 40% Section 482 Penalty. The IRS did not apply the 40% Section 482 Penalty to the amount the IRS claimed Plaintiff owed under its asserted Section 482 Alternative Theory, but instead applied it to the amount the IRS claimed Plaintiff owed under its asserted primary common-law theories. The 40% Section 482 Penalty cannot be sustained based on the primary common-law theories.

ANSWER: Admits that the IRS assessed a 40% gross valuation misstatement penalty, citing IRC sections 6662(a), 6662(b)(3), 6662(e), and 6662(h); otherwise, denies.

78. With respect to Plaintiff’s deductions for the 2011 and 2012 tax years of ¶ IV ANDA patent litigation defense costs, although the IRS did not dispute the amounts of the legal fees and expenses that Plaintiff paid or incurred defending against patent infringement lawsuits or that such costs are generally deductible under IRC section 162 as ordinary and necessary business expenses, the IRS denied the claims for refund on the basis that the amounts Plaintiff paid or incurred should be capitalized rather than currently deducted (the “capitalization theory”).

ANSWER: Admits that the IRS denied Plaintiff’s claims for refund; admits that the IRS, in its notice of deficiency for Plaintiff’s 2011 and 2012 tax years did not dispute the amounts of legal fees and expenses that Plaintiff paid or incurred defending against patent

infringement lawsuits; admits that the IRS made adjustments reflected in the notice of deficiency on the basis that the amounts Plaintiff paid or incurred should be capitalized rather than currently deducted; otherwise, lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph; and avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff's tax returns.

79. The IRS bases its capitalization theory on two arguments. First, the IRS contends that the "origin-of-the-claim" doctrine mandates capitalization because the "origin" of the patent infringement claims was Plaintiff's filing of ¶ IV ANDAs. Second, the IRS contends that the regulations promulgated under IRC section 263 require capitalization because the patent litigation defense costs were "transaction costs" that "facilitated" FDA approval of the ¶ IV ANDAs.

ANSWER: Admits that the IRS, in a notice of deficiency for the 2011 and 2012 tax years, contended that legal fees incurred relating to the filing of ANDAs, with ¶ IV certifications, are properly capitalized under I.R.C. § 263 and Treas. Reg. § 1.263(a)-4; and avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff's tax returns.

80. Based on its capitalization theory, the IRS reduced Plaintiff's deductions for the 2011 and 2012 tax years by \$2,185,376 and \$7,062,889, respectively.

ANSWER: Admits that the IRS made these adjustments, as reflected in the notice of deficiency for the 2011 and 2012 tax years; and avers that the IRS made a corresponding adjustment for Plaintiff's 2012 tax year to increase Plaintiff's deduction under I.R.C. § 197 by \$143,273.

81. In addition, the IRS treated the adjustment to Plaintiff's income based on its capitalization theory as a change in method of accounting requiring an IRC section 481 adjustment in the 2011 tax year increasing income for that year in the amount of \$12,651,062 (the "section 481 adjustment").

ANSWER: Admits that the IRS made these adjustments, as reflected in the notice of deficiency for the 2011 and 2012 tax years.

82. The foregoing IRS theories and assertions are erroneous, illegal, and not grounds to keep Plaintiff's money.

ANSWER: Denies; avers that the United States is not bound by IRS contentions made in the context of the examination of Plaintiff's tax returns; and further avers that Plaintiff bears the burden of proving the amount it seeks to recover in this tax refund suit.

COUNT ONE: 2009 TAX YEAR

83. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 82, supra.

ANSWER: Defendant incorporates by reference the responses to those allegations.

84. The IRS's sham entity theory lacks factual and legal basis. The reasons include that PITLP/LLC was formed as part of Plaintiff's intended internationalization of its business operations and that PITLP/LLC conducted bona fide business activities.

ANSWER: Denies.

85. The IRS's sham transaction theory lacks factual and legal basis. The Assignment Agreement did not lack economic substance under the standards set forth in the regulations promulgated under IRC section 482, which render the common-law economic substance doctrine inapplicable to the assignment transaction. Even if the common-law doctrine applied, the

assignment of the Contract possessed non-tax substance and satisfies both the objective and subjective prongs of the economic substance doctrine.

ANSWER: Denies.

86. The IRS's assignment-of-income theory lacks factual and legal basis. The reasons include that the assignment-of-income doctrine does not apply, that the Assignment Agreement shifted ownership of the rights and obligations imposed by the Contract to PITLP/LLC, and that the assignment of the Contract was not an anticipatory assignment of income.

ANSWER: Denies.

87. The IRS's Section 482 Alternative Theory, which allocates nearly all of the income of PITLP/LLC to Plaintiff, is unreasonable, arbitrary and capricious, an abuse of the IRS's discretion, without factual basis, and legally erroneous, and fails to produce an arm's-length result. Respective payments and incomes of PITLP/LLC and Plaintiff from the Contract and transactions related to the sale and distribution of generic OTC omeprazole reflected arm's-length results under the principles of IRC section 482 and the regulations promulgated thereunder.

ANSWER: Denies.

88. The IRS's 40% Section 482 Penalty and 20% Section 482 Penalty do not apply. Those penalties are inapplicable because the IRS's Section 482 Alternative Theory is erroneous and contrary to law and therefore there was no valuation misstatement. Even if the IRS's Section 482 Alternative Theory were not illegal and erroneous, the IRS's 40% Section 482 Penalty and 20% Section 482 Penalty do not apply because Plaintiff satisfied the requirements of IRC section 6662(e)(3)(B)(i), including that Plaintiff applied appropriate transfer pricing methods to price the

assignment of the Contract and transactions related to the sale and distribution of generic OTC omeprazole in a reasonable manner and in good-faith reliance on EY's professional tax advice.

ANSWER: Denies.

89. The IRS's 20% Substantial Understatement Penalty does not apply because there is no understatement of tax to which the penalty can apply, substantial authority existed for Plaintiff's tax treatment, and Plaintiff reasonably and in good-faith relied on EY's professional tax advice.

ANSWER: Denies.

90. The IRS's 20% Negligence or Disregard Penalty does not apply because there is no negligence or disregard of the rules or regulations as those terms are defined in IRC section 6662(c), Plaintiff had a reasonable basis for its tax treatment, and Plaintiff reasonably and in good-faith relied on EY's professional tax advice.

ANSWER: Denies.

91. Accordingly, with respect to the 2009 tax year Plaintiff is entitled to a refund of assessed and overpaid tax, penalties, and interest of \$37,221,289, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest thereon as provided by law.

ANSWER: Denies.

COUNT TWO: 2010 TAX YEAR

92. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 91, supra.

ANSWER: Defendant incorporates by reference the responses to those allegations.

93. Accordingly, with respect to the 2010 taxable year Plaintiff is entitled to a refund of assessed and paid tax, penalties, and interest of \$61,462,133, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest as provided by law.

ANSWER: Denies.

COUNT THREE: 2011 TAX YEAR

94. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 93, supra.

ANSWER: Defendant incorporates by reference the responses to those allegations.

95. The IRS's capitalization theory lacks factual and legal basis. The reasons include that a patent holder's legal rights to protect its patented drugs arise under the patent laws and not under the food and drugs laws, that the origin of the claim doctrine otherwise does not apply because regulations promulgated under IRC section 263(a) govern all issues related to capitalization of intangible assets and preempt preexisting common law principles, and that under those regulations patent litigation defense costs do not facilitate the acquisition of a ¶ IV ANDA within the meaning of Treasury Regulation section 1.263(a)-4 and therefore the costs are not subject to capitalization.

ANSWER: Denies.

96. The IRS's section 481 adjustment lacks factual and legal basis. Because the IRS's argument under its capitalization theory that Plaintiff's ¶ IV ANDA patent litigation costs must be capitalized is illegal and erroneous, the IRS's section 481 adjustment is likewise invalid.

ANSWER: Denies.

97. Accordingly, with respect to the 2011 taxable year Plaintiff is entitled to a refund of assessed and paid tax, penalties, and interest of \$40,148,650, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest as provided by law.

ANSWER: Denies.

COUNT FOUR: 2012 TAX YEAR

98. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 97, supra.

ANSWER: Defendant incorporates by reference the responses to those allegations.

99. Accordingly, with respect to the 2012 taxable year Plaintiff is entitled to a refund of assessed and paid tax, penalties, and interest of \$24,730,253, or such greater amount of overpayment that may be determined to be due and owing Plaintiff, plus interest as provided by law.

ANSWER: Denies.

COUNT FIVE: INTEREST NETTING

100. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 99, supra.

ANSWER: Defendant incorporates by reference the responses to those allegations.

101. To the extent there are overlapping underpayments and overpayments of tax for the tax periods at issue, Plaintiff is entitled to net interest in accordance with the interest netting provisions of IRC section 6621(d).

ANSWER: Lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph.

COUNT SIX: RELATED ADJUSTMENTS

102. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 101, supra.

ANSWER: Defendant incorporates by reference the responses to those allegations.

103. Plaintiff reserves the right to challenge or assert any setoffs or adjustments, correlative or otherwise, that flow from any calculations, positions of Defendant, changes in law or final determinations by this Court in connection with this case.

ANSWER: This statement does not constitute an allegation of fact and requires no response.

FIRST ADDITIONAL DEFENSE

From its inception in late 2006, Perrigo LLC (formerly named Perrigo Israel, LLC) (“LLC”) has not engaged in substantive business activity, and its purported income has not been taxed in the United States or, on information and belief, in Israel. LLC performs no valid economic function.

On information and belief, at all relevant times, LLC had no employees of its own; its officers were employees of Plaintiff; it had no offices or operational facilities of its own; it had no assets with which to “purchase” distribution rights to Dexcel’s omeprazole product from Plaintiff;² and Dexcel’s omeprazole product was shipped directly from Dexcel to Plaintiff, where it was then distributed and sold by Plaintiff.

LLC’s purported transactions with Plaintiff relating to omeprazole prior to and during the tax years at issue lack substance and should be disregarded. LLC itself is a

² References to “Plaintiff” in Defendant’s first additional defense are intended to encompass L. Perrigo Company, a subsidiary of Plaintiff, and a member of its consolidated return group.

sham and should be disregarded. Plaintiff's purported assignment of distribution rights, as well as its subsequent purported transfer payments to LLC relating to omeprazole sales, constitute an impermissible assignment of income.

In the alternative, income shifted from Plaintiff to LLC pursuant to an assignment of distribution rights (and related agreements) should be reallocated to Plaintiff pursuant to the Commissioner's authority under I.R.C. § 482.

SECOND ADDITIONAL DEFENSE

To the extent Plaintiff's bases for refunds set forth in the complaint were not contained in Plaintiff's claims for refunds, they constitute a variance from the claims for refund filed with the Internal Revenue Service. This Court lacks jurisdiction under 26 U.S.C. § 7422(a) to hear any such alternative claims.

PRAYER FOR RELIEF

No response is necessary as to the remainder of the complaint because it is a prayer for relief. The United States denies all allegations not otherwise specifically admitted, qualified or denied, and respectfully requests that the United States be awarded costs and such other relief as appropriate.

DATED this 17th day of October, 2017

(signature block follows on next page)

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of October, 2017, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the following:

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In addition, I sent copies of the foregoing, by first-class mail, postage prepaid, to the following:

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